K042787

DEC 17 2004

8. SMDA Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

SATELEC
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33708 Merignac Cedex
FRANCE

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Contact Person: Steve Salesky
SATELEC
c/o Acteon, Inc.
130 Gaither Drive, Suite 100
Mt. Laurel, NJ 08054
Telephone: 856 222-9988
Fax: 856 222-4726

Date Prepared: October 4, 2004

B. Device Identification

Common Usual Name: Micromotor
Proprietary Name: IS 40 Micromotor

C. Identification of predicate Device

The Satelec IS 40 Micromotor is substantially equivalent to the predicate device by Dentsply International, the eStylus™ Electric Motor System (K031145) previously cleared by the FDA and currently marketed.

D. Device Description

The IS 40 Micromotor with internal spray is compatible with all types of contra-angles that have an E-type connection and internal spray. The IS 40 Micromotor is used with Satelec Cocoon® Hygienist (K040529) which incorporates the M6 module with automatic servo control for motor power and speed control. IS 40 Micromotor operates at a speed from 1,600 to 40,000 rpm and provides a torque of 1.6 Newton/cm at 3 A.

The intended use is in general dentistry for cutting, shaping, drilling, cleaning, prophylaxis and polishing of teeth by dental professionals.

E. Substantial Equivalence

The IS 40 Micromotor and the predicate device, eStylus™ Electric Motor System, are both electric motor driven dental handpieces for use with various attachments intended for use in general dentistry. Differences that exist between the devices relating to technical specifications, performances and intended use are minor and do not affect the safety and effectiveness of the IS 40 Micromotor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

SATELEC
C/O Mr. Steve Salesky
Acteon, Incorporated
130 Gaither Drive, Suite 100
Mt. Laurel, New Jersey 08054

Re: K042787
Trade/Device Name: IS 40 Micromotor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: October 4, 2004
Received: October 6, 2004

Dear Mr. Salesky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

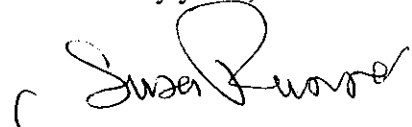
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042787

Device Name: IS 40 Micromotor

Indications for Use:

The intended use of the IS40 Micromotor is in general dentistry for cutting, shaping, drilling, cleaning, prophylaxis and polishing of teeth by dental professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042787